

Exhibit 1

OPINION

Break Up the Insulin Racket

By Kasia Lipska

Feb. 20, 2016

ONE of my patients — whom I will call Mrs. B — is a 78-year-old who has had Type 2 diabetes for over 30 years. She takes several injections of insulin each day. Her blood sugars have been running too high, but she doesn't want to increase the dose of her insulin. She told me she simply can't afford to.

Insulin has been around for almost a century. The World Health Organization considers it an essential medicine, which means it should be available “at a price the individual and the community can afford.” So why is this product increasingly too expensive for many Americans?

In the United States, just three pharmaceutical giants hold patents that allow them to manufacture insulin: Eli Lilly, Sanofi and Novo Nordisk. Put together, the “big three” made more than \$12 billion in profits in 2014, with insulin accounting for a large portion.

What makes this so worrisome is that the big three have simultaneously hiked their prices. From 2010 to 2015, the price of Lantus (made by Sanofi) went up by 168 percent; the price of Levemir (made by Novo Nordisk) rose by 169 percent; and the price of Humulin R U-500 (made by Eli Lilly) soared by 325 percent.

To make insulin affordable, we need more competition. Nothing would do this faster than a “generic” form of insulin. (Technically, because insulin is made using bacteria, it should be referred to as a “biosimilar” instead of a “generic.”) Unfortunately, there isn't one available in the United States.

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This is true, in no small part, because the big three have cleverly extended the lives of their patents, making incremental “improvements” to their insulin. It’s not clear whether the newer insulin products are significantly safer or more effective than their predecessors, yet the strategy has been effective: There is no generic insulin, and over 90 percent of privately insured patients with Type 2 diabetes who are prescribed insulin get the newer and more expensive products.

But even a generic version of insulin might not solve all of Mrs. B’s problems. Something else is most likely contributing to the rising price of insulin: a very powerful and largely invisible group of middlemen, known as pharmacy benefit managers, or P.B.M.s.

Benefit managers negotiate with drug companies on behalf of insurers, such as employer plans and government programs like Medicaid and Medicare Part D. In theory, their job is to bargain for lower drug prices.

The hitch is that the biggest P.B.M.s are out to make a buck. They get “rebates” from drug manufacturers — payments based on sales or other criteria, which look suspiciously similar to kickbacks. The rebates are not publicly disclosed, but they are sizable. Industry analysts estimate that those payments, and other back-room deals, amount to as much as 50 percent of the list price of insulin.

This, of course, creates a conflict of interest. Benefit managers are supposed to be driving down costs, but the system incentivizes them to choose the products with the largest rebates. It’s not clear whether most of these “savings” are passed along to consumers or simply pocketed. Last month, a large insurer, Anthem, complained publicly that its P.B.M., Express Scripts, was not sharing enough of its savings.

What we do know is that business is booming for P.B.M.s. Together, the three biggest benefit managers — Express Scripts, CVS Health and OptumRx — bring in more than \$200 billion a year in revenue. They also control over 80 percent of the P.B.M. market, involving 180 million insured people.

Where does this leave my patient? Mrs. B has Medicare Part D coverage. She is responsible for co-payments on her insulin. But every year, by early fall, she typically reaches a coverage gap (known as the doughnut hole) when she becomes responsible for paying for insulin out of pocket. So Mrs. B skimps on her medicine, allowing her blood sugar to rise to worrisome levels.

There is some hope that the insulin industry is about to become more competitive. The patent on Lantus (Sanofi's top-selling insulin) recently expired, allowing other companies to start preparing generic forms. The first generic competitor usually sets a price that is only slightly below the branded insulin. Research shows that once there are two manufacturers of a generic drug, the price typically drops by about half; with eight, it drops to about a fifth. But because insulin is a biosimilar, the decline may be more modest. And this will take time; additional testing is needed to ensure the safety and effectiveness of each new generic before it is approved.

IN the meantime, we need a fair and transparent system for setting prices. In much of Europe, insulin costs about a sixth of what it does here. That's because the governments play the role of pharmacy benefit managers. They negotiate with the manufacturer directly and have been very effective at driving down prices. In the United States, we rely on the private sector and a free market for drug pricing. But in order for this to work, we need to regulate it better and demand greater transparency.

Over the past 10 years, the Federal Trade Commission has brought only a single enforcement action against benefit managers, over an issue of patient privacy violations.

There are some short-term solutions in the hands of patients and doctors. After talking with Mrs. B, I prescribed an older, slightly cheaper version of insulin — known as “human” insulin — which worked just as well. In fact, it is more effective because she is actually taking it.

In general, our faith in newer and “better” drugs — coupled with our unwillingness to police this marketplace — has done little to help Americans like Mrs. B. Sure, we need to protect the intellectual capital of pharmaceutical companies so that they continue to invest in innovative new drugs. But those drugs should ultimately result in better health for patients, not just wider profit margins.

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A version of this article appears in print on , Section SR, Page 5 of the New York edition with the headline: Break Up the Insulin Racket